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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,240	03/23/2004	Giovanni Caponetti	250893US0CONT	1764

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EXAMINER
ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
11/08/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/806,240	CAPONETTI ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-29 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-29 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 22-29 and 31-33 are pending. Applicants previously cancelled claims 1-21 and 30. Applicants have amended claims 22-24 and 32. Receipt and consideration of Applicants' amended claim set and remarks/arguments submitted on August 6, 2007 are acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 5, 2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.

3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 22-29 and 31-33 under 35 U.S.C. 103(a) as being unpatentable over Ganderton et al. (U.S. Patent No. 5,376,386) in view of Kato et al. (EP 0786526; IDS) **is withdrawn** per Applicants' claim amendments requiring that the particles made by the claimed process are unagglomerated.

Response to Arguments

Applicant's arguments, see pages 6-10, filed August 6, 2007, with respect to the rejection of claims 22-29 and 31-33 under 35 U.S.C. 103(a) as being unpatentable over Ganderton et al. (U.S. Patent No. 5,376,386) in view of Kato et al. (EP 0786526; IDS) have been fully considered and are persuasive. The rejection of claims 22-29 and 31-33 under 35 U.S.C. 103(a) as being unpatentable over Ganderton et al. (U.S. Patent No. 5,376,386) in view of Kato et al. (EP 0786526; IDS) has been withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection on the ground of nonstatutory obviousness-type double patenting of claims 22-29 and 32-33 as being unpatentable over claims 1-12 of U.S. Patent No. 6,780,508 (USPN '508) **is withdrawn** upon reconsideration.

Response to Arguments

Applicant's arguments with respect to claims 22-29 and 32-33 have been considered but are moot in view of the new ground(s) of rejection.

Claims 22-29 and 32-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,780,508 (USPN '508) in view of Ganderton (U.S. Patent No. 5,376,386).

Independent claim 22 of the instant application claims a process of preparing a carrier comprising, subjecting a first plurality of un-agglomerated particles having a median diameter of greater than 90 microns and a surface rugosity expressed as the fractal dimension of greater than 1.1 to repeated stages of wetting with a solvent and drying in a high-speed granulator, wherein said solvent is a short-chain aliphatic alcohol or a water and alcohol mixture to obtain a 2nd plurality of un-agglomerated particles having a median diameter of greater than 90 microns and a surface rugosity expressed as the fractal dimension of greater than 1.1. Independent claim 9 of USPN '508 claims a process for preparing a carrier as claimed in claim 1 (i.e. median diameter > 90 microns and a surface rugosity of less than or equal to 1.1) comprising subjecting a first plurality of un-agglomerated particles having a median diameter of greater than 90 microns to repeated stages of wetting with a solvent. Dependent claim 10 of USPN '508 indicates that the repeated stages of wetting and drying are carried out in a high-speed granulator. The primary differences between the claims of the instant application and those of USPN '508 are that (a) the claimed process of '508 does not specify the solvent utilized is a short-chain alcohol, water, or a mixture thereof and (b) the process of USPN '508 produces carrier particles with a surface rugosity of less than or equal to 1.1. Ganderton is provided to demonstrate that it is conventional to expose carrier particles (e.g. lactose) to repeated stages of wetting with ethanol or ethanol/water mixtures (col. 3, lines 8-17). Regarding the difference of the claimed surface rugosity of the instant claims and those of USPN '508, it is would well be within the capability

of an ordinary skilled artisan to utilize substantially similar processes as claimed by Applicants in the instant application and in USPN '508 to vary the surface rugosity of the obtained particles. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 22-29 and 32-33 *prima facie* obvious over claims 1-22 of U.S. Patent No. 6,780,508 (USPN '508) in view of Ganderton (U.S. Patent No. 5,376,386).

Conclusion

Claims 22-29 and 31-33 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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